

## WHAT IS CLAIMED IS:

- 1. A nucleic acid-cationic immunoliposome complex comprising i) a cationic liposome, ii) an antibody or antibody fragment, and iii) a nucleic acid wherein said nucleic acid-cationic immunoliposome complex is prepared by a method comprising the steps of:
  - a) mixing said nucleic acid with said cationic liposome to produce a nucleic acidliposome complex;
    - b) preparing said antibody or antibody fragment; and
    - c) mixing said nucleic acid-fiposome complex with said antibody or antibody fragment to form said nucleic acid-cationic immunoliposome complex; or
  - 2) a) preparing said antibody or antibody fragment;
    - b) mixing said antibody or antibody fragment with said cationic liposome to form a cationic immunoliposome; and
    - c) mixing said cationic immunoliposome with said nucleic acid to form said nucleic acid-cationic immunoliposome complex.
- The nucleic acid-cationic immunoliposome complex of claim 1 wherein said antibody or antibody fragment is capable of binding to a transferrin receptor.
- 3. The nucleic acid-cationic immunoliposome complex of claim 1 wherein said nucleic acid is DNA.
- The nucleic acid-cationic immunoliposome complex of claim 1 wherein said nucleic acid encodes a wild type p53.
- 5. The nucleic acid-cationic immunoliposome complex of claim 1 wherein said antibody or antibody fragment comprises a lipid tag.
- 6. The nucleic acid-cationic immunoliposome complex of claim 1 wherein said antibody or antibody fragment is covalently bound to said cationic liposome via a sulfur atom which was part of a sulfhydryl group at a carboxy terminus on said antibody or antibody fragment.

- 7. The nucleic acid-cationic immunoliposome complex of claim 6 wherein said sulfur atom is part of a cysteine residue.
- 8. The nucleic acid-cationic immunoliposome complex of claim 6 wherein said antibody or antibody fragment is covalently bound to DOPE linked to MPB or other sulfnydryl reacting group.
- The nucleic acid-cationic immunoliposome complex of claim 1 wherein said antibody fragment is a single chain.
- 10. The nucleic acid-cationic immunoliposome complex of claim 1 wherein said antibody or antibody fragment and said cationic liposome are present at a protein:lipid ratio (w:w) in the range of 1:5 to 1:40.
- 11. The nucleic acid-cationic immunoliposome complex of claim 1 wherein said nucleic acid and said cationic liposome are present at a nucleic acid:lipid (μg:nmol) ratio in the range of 1:6 to 1:20.
- 12. A pharmaceutical composition comprising the nucleic acid-cationic immunoliposome complex of claim 1.
- 13. A method of preparing a nucleic acid-cationic immunoliposome complex comprising the steps of:
  - a) mixing nucleic acid with a cationic liposome to produce a nucleic acid-liposome complex;
  - b) preparing an antibody or antibody fragment; and
  - c) mixing said nucleic acid-liposome complex with said antibody or antibody fragment to form said nucleic acid-cationic immunoliposome complex.
- The method of claim 13 wherein said nucleic acid encodes a wild type p53.

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- 15. The method of claim 13 wherein said antibody or antibody fragment is capable of binding to a transferrin receptor.
- The method of claim 13 wherein said antibody or antibody fragment comprises a lipid tag.
- 17. The method of claim 13 wherein said antibody or antibody fragment comprises a reducible group at a carboxy terminus prior to mixing with said nucleic acid-liposome complex.
- 18. The method of claim 17 wherein said reducible group is a sulfhydryl.
- 19. The method of claim 18 wherein said sulfhydryl is part of a cystcine residue.
- 20. The method of claim 17 wherein said antibody or antibody fragment is covalently bound to said cationic liposome via a sulfur atom of said reducible group.
- 21. The method of claim 17 wherein said cationic liposome comprises DOPE linked to MPB or other sulfhydryl reacting group.
- 22. The method of claim 13 wherein said nucleic acid is DNA.
- 23. The method of claim 13 wherein said antibody or antibody fragment and said cationic liposome are present in said nucleic acid-cationic immunoliposome complex at a protein:lipid ratio (w:w) in the range of 1:5 to 1:40.
- 24. The method of claim 13 wherein said nucleic acid and said cationic liposome are present in said nucleic acid-cationic immunoliposome complex at a nucleic acid:lipid (μg:nmol) ratio in the range of 1:6 to 1:20.



- The method of claim 13 wherein said antibody fragment is a single chain. 25.
- A method of preparing a nucleic acid-cationic immunoliposome complex comprising the 26. steps of:
  - a) preparing an antibody or antibody fragment;
  - b) mixing said antibody or antibody fragment with a cationic liposome to form a cationic immunoliposome; and
  - c) mixing said cationic immunoliposome with nucleic acid to form said nucleic acidcationic immunoliposome complex.
- The method of claim 26 wherein said nucleic acid encodes a wild type p53. 27.
- The method of claim 26 wherein said antibody or antibody fragment is capable of binding 28. to a transferrin receptor.
- The method of claim 26 wherein said antibody or antibody fragment comprises a lipid 29. tag.
- 30. The method of claim 26 wherein said antibody or antibody fragment comprises a reducible group at a carboxy terminus prior to mixing with said nucleic acid-liposome complex.
- 31. The method of claim 30 wherein said reducible group is a sulfhydryl.
- 32. The method of claim 31 wherein said sulfhydryl is part of a cysteine residue.
- The method of claim 31 wherein said antibody or antibody fragment is covalently bound 33. to said cationic liposome via a sulfur atom of said reducible group.
- The method of claim 30 wherein said cationic liposome comprises MPB-DOPE. 34.



- 35. The method of claim 26 wherein said nucleic acid is DNA.
- 36. The method of claim 26 wherein said antibody or antibody fragment and said cationic liposome are present in said nucleic acid-cationic immunoliposome complex at a protein:lipid ratio (w:w) in the range of 1:5 to 1:40.
- 37. The method of claim 26 wherein said nucleic acid and said cationic liposome are present in said nucleic acid-cationic immunoliposome complex at a nucleic acid:lipid (µg:nmol) ratio in the range of 1:6 to 1:20.
- 38. The method of claim 26 wherein said antibody fragment is a single chain.
- 39. A method for providing a therapeutic molecule to an animal in need thereof, comprising administering to said animal a therapeutically effective amount of a nucleic acid-cationic immunoliposome complex comprising i) a cationic liposome, ii) an antibody or antibody fragment, and iii) a nucleic acid wherein said nucleic acid-cationic immunoliposome complex is prepared by a method comprising the steps of:
  - a) mixing said nucleic acid with said cationic liposome to produce a nucleic acidliposome complex;
    - b) preparing said antibody or antibody fragment; and
    - c) mixing said nucleic acid-liposome complex with said antibody or antibody fragment to form said nucleic acid-cationic immunoliposome complex; or
  - a) preparing said antibody or antibody fragment;
    - b) mixing said antibody or antibody fragment with a cationic liposome to form a cationic immunoliposome; and
    - c) mixing said cationic immunoliposome with said nucleic acid to form said nucleic acid-cationic immunoliposome complex.
- The method of claim 39 wherein said complex is administered systemically.
- 41. The method of claim 39 wherein said complex is administered intravenously.

- 42. The method of claim 39 wherein said antibody or antibody fragment is capable of binding to a transferrin receptor.
- 43. The method of claim 39 wherein said antibody fragment is a single chain.
- 44. The method of claim 39 wherein said nucleic acid is DNA.
- 45. The method of claim 39 wherein said nucleic acid encodes a wild type p53.
- 46. The method of claim 39 wherein said antibody or antibody fragment comprises a lipid tag.
- 47. The method of claim 39 wherein said antibody or antibody fragment is covalently bound to said cationic liposome via a sulfur atom which was part of a reducible group at a carboxy terminus on said antibody or antibody fragment.
- 48. The method of claim 47 wherein said reducible group is a sulfhydryl.
- 49. The method of claim 48 wherein said sulfhydryl is part of a cysteine residue.
- 50. The method of claim 47 wherein said antibody or antibody fragment is covalently bound to DOPE linked to MPB or other sulfhydryl reacting group.
- 51. The method according to claim 39 wherein said antibody or antibody fragment and said cationic liposome are present in said nucleic acid-cationic immunoliposome complex at a protein: lipid ratio (w:w) in the range of 1:5 to 1:40.
- 52. The method according to claim 39 wherein said nucleic acid and said cationic liposome are present in said nucleic acid-cationic immunoliposome complex at a nucleic acid:lipid (µg:nmol) ratio in the range of 1:6 to 1:20.



- The method according to claim 39 wherein said animal is a human. 53.
- The method according to claim 39 wherein said animal has cancer. 54.
- The method according to claim 54 wherein said cancer is selected from the group 55. consisting of i) head and neck cancer, ii) breast cancer and iii) prostate cancer.
- 56. A kit comprising
  - i) a nucleic acid;
  - ii) a cationic immunoliposome; and
  - iii) an instruction manual for preparing a nucleic acid-cationic immunoliposome complex prepared by a method comprising the steps of:
  - a) mixing said nucleic acid with said cationic liposome to produce a nucleic acid-1) liposome complex;
    - b) preparing an antibody or antibody fragment; and
    - c) mixing said nucleic acid-liposome complex with said antibody or antibody fragment to form said nucleic acid-cationic immunoliposome complex; or
  - 2) a) preparing an antibody or antibody fragment;
    - b) mixing said antibody or antibody fragment with said cationic liposome to form a cationic immunoliposome; and
    - c) mixing said cationic immunoliposome with said nucleic acid to form said nucleic acid-cationic immunoliposome complex.
- 57. The kit of claim 56 wherein said nucleic acid encodes a wild type p53.
- The kit of claim 56 wherein said cationic liposome comprises an antibody or antibody 58. fragment capable of binding to a transferrin receptor.
- The kit of claim 56 wherein said antibody fragment is a single chain. **5**9.

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- The kit of claim 56 wherein said antibody fragment comprises a lipid tag. 60.
- The kit of claim 56 wherein said antibody fragment is conjugated to a cationic liposome. 61.
- The kit of claim 56 said antibody fragment and cationic lipids are present in a 62. protein:lipid ratio (w:w) in the range of 1:5 to 1:40.
- The kit of claim 56 wherein said cationic immunoliposome is in an aqueous solution. 63.
- The kit of claim 56 further comprising a nucleic acid for use as a positive control in a б4. container separate from said cationic immunoliposome.
- The kit of claim 64 wherein said nucleic acid encodes a reporter gene selected from the 65. group consisting of luciferase, β-galactosidase and green fluoreseent protein.
- 66. A method of transfecting cells with a desired nucleic acid wherein said method comprises administering the nucleic acid-cationic immunoliposome complex of the kit of claim 56 to said cells wherein said complex comprises said desired nucleic acid.
- The method of claim 66 wherein said method is performed in vitro. 67.
- 68. A method of transfecting cells in a tissue in an animal with a desired nucleic acid wherein said method comprises administering the nucleic acid-cationic immunoliposome complex of the kit of claim 56 to said cells wherein said complex comprises said desired nucleic acid.